

Approval Date: NOV 14 2005

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION

ANADA 200-376

SULFAMED-G Soluble Powder
(sodium sulfadimethoxine)

For treatment of coccidiosis or various bacterial diseases in
chickens, turkeys, and cattle

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY**1. GENERAL INFORMATION:**

- a. File Number: ANADA 200-376
- b. Sponsor: Cross Vetpharm Group Ltd.
Broomhill Road, Tallaght
Dublin 24, Ireland
- Drug Labeler Code: 061623
- US Agent: Linda M. Duple
Director, North American Regulatory Affairs
Bimeda, Inc.
A Division of Cross Vetpharm Group Ltd.
2836 Dolliver Park Ave.
Lehigh, IA 50557
- c. Established Name: Sodium sulfadimethoxine
- d. Proprietary Name: SULFAMED-G Soluble Powder
- e. Dosage Form: Soluble powder
- f. How Supplied: 107 g (3.77 oz) pouch
535 g (18.87 oz) pouch
25 lb (11.34 kg) pail
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 107 g (3.77 oz) pouch: each packet contains
3.34 oz (94.6 g) Sulfadimethoxine in the
form of the soluble sodium salt and
disodium edetate.
- 535 g (18.87 oz) pouch: each packet
contains 16.8 oz (473 g) Sulfadimethoxine
in the form of the soluble sodium salt and
disodium edetate.
- 25 lb (11.34 kg) pail: 3 scoops contain 3.34
oz (94.6 g) Sulfadimethoxine in the form of
the soluble sodium salt and disodium
edetate.

- i. Route of Administration: Oral
- j. Species/Class: Broiler and replacement chickens, meat-producing turkeys, dairy calves, dairy heifers, and cattle
- k. Recommended Dosage: Chickens: 1.875 (0.05 percent) grams per gallon of drinking water in automatic proportioners for six days.
Turkeys: 0.938 (0.025 percent) grams per gallon of drinking water in automatic proportioners for six days.
Cattle: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 four days or 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon. Administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days.
- l. Pharmacological Category: Antimicrobial, anticoccidial
- m. Indications: ***For Broiler and Replacement Chickens Only:*** Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.
For Meat-producing Turkeys Only: Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.
For Dairy Calves, Dairy Heifers, and Beef Cattle: Use for the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.
- n. Pioneer Product: ALBON; sodium sulfadimethoxine; NADA 046-285; Pfizer, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product SULFAMED-G (sodium sulfadimethoxine) Soluble Powder. The generic product is administered as an oral solution, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, ALBON (sodium sulfadimethoxine) Soluble Powder, the subject of Pfizer, Inc., NADA 046-285, was approved on June 17, 1992.

3. **HUMAN SAFETY:**

- **Tolerances for Residues:**

The tolerance established for the pioneer product applies to the generic product. A tolerance 0.01 ppm is established for sulfadimethoxine residues in milk and uncooked edible tissues of chickens, turkeys and cattle under 21 CFR 556.640.

- **Withdrawal Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal times are 5 days for chickens and turkeys, and 7 days for cattle.

- **Regulatory Method for Residues:**

The analytical method for determination of sulfadimethoxine in tissues uses a thin layer-densitometric procedure. This method is found in the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 15th edition, 1990.

The method is available from the Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

4. **AGENCY CONCLUSIONS:**

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that SULFAMED-G Soluble Powder, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-376:

SULFAMED-G Soluble Powder

107 g (3.77 oz) pouch, front and back

107 g (3.77 oz) 25 packets label

535 g (18.87 oz) pouch, front and back

535 g (18.87 oz) 20 packets label

25 lb (11.34 kg) pail, front and back

Pioneer Labeling for NADA 046-285:

ALBON Soluble Powder

107 g (3.77 oz) pouch, front and back

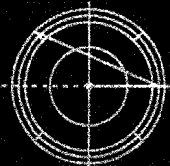
5.5"

SulfaMed-G™

(brand of Sulfadimethoxine)

Soluble Powder

Antibacterial



For Oral Use in Chickens, Turkeys and Cattle

FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy cattle.

Restricted Drug - Use Only as Directed (California)

INDICATIONS:

For Broiler and Replacement Chickens Only - Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only - Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle - Use for the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

NET WEIGHT: 107 g (3.77 oz)

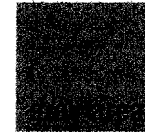
Each packet contains 3.34 oz (94.6 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edelate.

Manufactured by: Bimeda, Inc.
Le Sueur, MN 56058
Bimeda, Inc. is a division of Cross Vetpharm Group, Ltd.

SulfaMed-G is a Trademark of Bimeda, Inc.
ANADA 200-376, Approved by FDA



Bimeda



represents
non-print area
for 3/8" seal



yellow area
represents
pattern varnish
4.75" x 5.75"

4.5" X 5.5"
image area
front/back

5.5" X 7.5"
pouch size

.5" X 1"
eyemark

2" oap

**2" gap
bottom of pouch**

PROOF

THIS PROOF IS TO CHECK FOR ACCURACY

Please review and approve: **Copy, spelling, copy placement, size, shape, colors, unwind, and dieline.** **Authorized signature** accepts responsibility for accuracy of all copy, color break and artwork. Lofton Label, Inc. is not liable for any discrepancies subsequently identified.

If proof is correct, check "O.K. AS IS", sign and return proof to expedite order. If corrections are necessary, check "Revised Proof Needed".

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Date _____

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(651) 457-8118 • FAX (651) 457-3709
6290 Claude Way E., Inver Grove Hts., MN 55076

JOB # **54040** DATE **9/8/05**

PAGE **1** of **1**

Size: 14.92" X 5.5" Cont.
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 LOF-LO

Rev. 10

1 - Black
2 - 248 Purple
3 - 877 Silver

SulfaMed-G™

(brand of Sulfadimethoxine)

Soluble Powder

Antibacterial

For Oral Use in Chickens, Turkeys and Cattle

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy cattle.

Restricted Drug - Use Only as Directed (California)

Net Contents: 25 Packets

Each Containing: 107 g (3.77 oz)

Each packet contains 3.34 oz (94.6 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

TAKE TIME  OBSERVE LABEL DIRECTIONS

Manufactured by: Bimeda, Inc.
Le Sueur, MN 56058
Bimeda, Inc. is a Division of Cross Vefpharm Group, Ltd.
ANADA 200-376, Approved by FDA



Sulfadimethoxine is a Trademark of Bimeda, Inc.

LOT:
EXP:

Product No: 1SDM005
SSDM010-705



Inside Yellow Dash
is Not Varnished.

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6290 Claude Way E., Inver Grove Hts., MN 55076

JOB # 54036 DATE 9/8/05

PAGE 1 of 1

Size: 5" x 4" RCR

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Rev. #8



LOF-L0

Colors:

- 1 - Black
- 2 - PMS 248 Purple
- 3 - PMS 877 Silver
- 4 - Pattern Varnish

9.25"

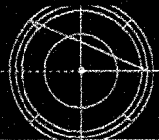
SulfaMed-G™

(brand of Sulfadimethoxine)

Soluble Powder

Antibacterial

For Oral Use in Chickens, Turkeys and Cattle



FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy cattle.
Restricted Drug - Use Only as Directed (California)

INDICATIONS:

For Broiler and Replacement Chickens Only - Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only - Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle - Use for the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

NET WEIGHT: 535 g (18.87 oz)

Each packet contains 16.8 oz (473 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Manufactured by: Bimeda, Inc.
Le Sueur, MN 56058
Bimeda, Inc. is a division of Cross Vetpharm Group, Ltd.

SulfaMed-G is a Trademark of Bimeda, Inc.
ANADA 200-376. Approved by FDA



Bimeda

represents
non-print area
for 3/8" seal

yellow area
represents
pattern varnish
6.75" x 7.25

6.5" X 7"
image area
front/back

9.25" X 9.5"
pouch size

.5" X 1"
eyemark

2.5" gap
bottom of pouch

19"

19"

PROOF

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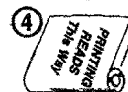
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PAGE 1 of 1

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Rev. 11

Colors:

1 - Black
2 - 248 Purple
3 - 877 Silver

SulfaMed-G™

(brand of Sulfadimethoxine)

Soluble Powder

Antibacterial

For Oral Use In Chickens, Turkeys and Cattle

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy cattle.

Restricted Drug - Use Only as Directed (California)

Net Contents: 20 Packets

Each Containing: 535 g (18.87 oz)

Each packet contains 16.8 oz (473 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Product No: 1SDM008
8SDM012-705



TAKE TIME



OBSERVE LABEL
DIRECTIONS

Manufactured by: Bimeda, Inc.
Le Sueur, MN 56058

Bimeda, Inc. is a Division of Cross Veterinary Group, Ltd.

ANADA 200-376, Approved by FDA



Bimeda

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LOT:
EXP:

Inside Yellow Dash
is Not Varnished.

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JOB # 54034 DATE 9/8/05

PAGE 1 of 1

Size: 5" X 4" RCR

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PRINTING
READS
This Way

LOF-L0

Rev. 10

Colors:

- 1 - Black
- 2 - 248 Purple
- 3 - 877 Silver

SulfaMed-GTM

(brand of Sulfadimethoxine)

Soluble Powder

Antibacterial

For Oral Use in Chickens, Turkeys and Cattle

FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy cattle.

Restricted Drug - Use Only as Directed (California)

INDICATIONS:

For Broiler and Replacement Chickens Only - Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only - Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle - Use for the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

NET WEIGHT: 25 lb. (11.34 kg)

3 scoops contain 3.34 oz (94.6 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Manufactured by: Bimeda, Inc.
Le Sueur, MN 56058
Bimeda, Inc. is a division of
Cross Vetpharm Group, Ltd.

SulfaMed-G is a Trademark of Bimeda, Inc.
ANADA 200-376, Approved by FDA



DOSAGE AND ADMINISTRATION

Species	Concentration	Use Directions
Chickens	0.05%	3 scoops in 50 gallons of water
Turkeys	0.025%	3 scoops in 100 gallons of water

If animals show no improvement within 5 days, discontinue treatment and re-evaluate diagnosis. Prepare a fresh stock solution daily. Handle the recommended dilutions (chickens 0.05% and turkeys 0.025%) as regular drinking water. Administer at sole source of drinking water and maintain the location.

Chickens and turkeys that have survived foot cholera outbreaks should not be kept for replacements or breeders.

Automatic Proportions - To make stock solution, add contents of 15 scoops to 2 gallons of water for chickens and to 4 gallons of water for turkeys. Set proportioner to feed at rate of 1 lb. of stock solution per gallon of water.

TREATMENT PERIOD - 5 consecutive days

Dairy Calves, Dairy Heifers and Beef Cattle

Dosage: 25 mg/lb. first day followed by 12.5 mg/lb. for 4 days.

SulfaMed-G in Water

WATER CONSUMPTION

	Amount of Stock Solution for Cattle*	(Summer) 1 gallon/100 lb. body weight	(Winter) 1 gallon/160 lb. body weight
First Day Add	1 quart 2 quarts 1 gallon	10 gallons 20 gallons 40 gallons	7 gallons 14 gallons 28 gallons
Next 4 Days Add	1 quart 2 quarts 1 gallon	20 gallons 40 gallons 80 gallons	14 gallons 28 gallons 56 gallons

*Note: Make a cattle stock solution by adding 3 scoops of SulfaMed-G Soluble Powder to 1 gallon of water.

**This dosage recommendation is based on a water consumption of 1 gallon per 100 lb. of body weight per day, the expected water consumption rate for summer. Water consumption during cold months (winter) may drop markedly (30-40%). Accordingly, adjustments must be made in the dilution rates to compensate for this and insure proper drug intake.

For treatment of individual cattle, SulfaMed-G Soluble Powder stock solution for cattle may be given as a drench.

Administer using same mg/lb. dosage as outlined above.

Twenty fl. oz. of cattle stock solution will medicate one 600 lb. animal initially or two 600 lb. animals on maintenance dose.

Contents of three scoops will medicate six 600 lb. animals initially or twelve 600 lb. animals on maintenance dose.

During treatment period, make certain that animals maintain adequate water intake.

If animals show no improvement within 2 or 3 days, re-evaluate diagnosis. Treatment should not be continued beyond 5 days.

RESIDUE WARNINGS: CHICKENS AND TURKEYS - Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age or to turkeys over 24 weeks (168 days) of age.

CATTLE - Withdraw 7 days before slaughter. For dairy calves, dairy heifers and beef cattle only. A withdrawal period has not been established for this product in pre-ruminating calves. Do Not Use in Calves to be Processed for Veal.



TAKE TIME



OBSERVE LABEL DIRECTIONS

Product No: 1SDM007
8SDM013-705

LOT:
EXP:

PROOF

THIS PROOF IS TO CHECK FOR ACCURACY
of the printed label. It is not to be used for
any other purpose. It is the responsibility of the
user to verify the accuracy of the printed label
by comparing it with the original label. If
it is found to be incorrect, check with the
manufacturer for a replacement. If necessary,
contact the manufacturer for a replacement.

WE CAN NOT PROCESS THIS ORDER WITHOUT
AN AUTHORIZED SIGNATURE

Signature: _____
Date: _____

Print Name To: _____

Address: _____

City: _____

State: _____

Zip: _____

Order No: _____

Date: _____

Size: 6" X 10" RCR

Decline does not print.

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Rev. 11

Colors:

1 - Black

2 - 877 Silver

3 - 248 Purple

4 - 107-L0

ALBON[®]

(Brand of Sulfadimethoxine)

ANTIBACTERIAL SOLUBLE POWDER

Each packet contains 3.34 oz (94.6 g) sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Restricted Drug (California)—Use Only as Directed

Not for Human Use

For Broiler and Replacement Chickens Only—Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only—Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle—Use for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.



7 47417 01813 5

Net wt 3.77 oz (107 g)

NADA #046-285, Approved by FDA

SB SmithKline Beecham

Dosage and Administration

Species	Concentration	Use Directions
Chickens	0.05%	Contents of packet to 50 gal of water
Turkeys	0.025%	Contents of packet to 100 gal of water

Automatic Proportioners—To make stock solution, add contents of 5 packets to 2 gal of water for chickens and to 4 gal of water for turkeys. Set proportioner to feed at rate of 1 fl oz stock solution per gal of water.
Treatment Period: 6 consecutive days

Dairy Calves, Dairy Heifers, and Beef Cattle

Dosage: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 days.

Albon (sulfadimethoxine) in Water

	Amount of Stock Solution for Cattle*	Water Consumption	
		(Summer) 1 gal/100 lb body wt**	(Winter) 1 gal/150 lb body wt**
First Day Add	1 qt	10 gal	7 gal
	2 qt	20 gal	14 gal
	1 gal	40 gal	28 gal
Next 4 Days Add	1 qt	20 gal	14 gal
	2 qt	40 gal	28 gal
	1 gal	80 gal	56 gal

*Note: Make a cattle stock solution by adding 1 packet of Albon Soluble Powder to 1 gal of water.

**Twenty fl oz of cattle stock solution will medicate 1 600-lb animal initially or 2 600-lb animals on maintenance dose. Contents of packet will medicate 6 600-lb animals initially or 12 600-lb animals on maintenance dose.

**This dosage recommendation is based on a water consumption of 1 gal per 100 lb of body weight per day, the expected water consumption rate for summer. Water consumption during cold months (winter) may drop markedly (30-40%). Accordingly, adjustments must be made in the dilution rates to compensate for this and insure proper drug intake.

For treatment of individual cattle, Albon (sulfadimethoxine) Soluble Powder stock solution for cattle may be given as a drench. Administer using same mg/lb dosage as outlined above.

Treatment Period: 5 consecutive days

Caution: Chickens and Turkeys—If animals show no improvement within 5 days, discontinue treatment and reevaluate diagnosis. Prepare a fresh stock solution daily. Handle the recommended dilutions (chickens 0.05% and turkeys 0.025%) as regular drinking water. Administer as sole source of drinking water and sulfonamide medication.

Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or breeders. **Cattle**—During treatment period, make certain that animals maintain adequate water intake. If animals show no improvement within 2 or 3 days, reevaluate diagnosis. Treatment should not be continued beyond 5 days.

Warning: Chickens and Turkeys—Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age or to turkeys over 24 weeks (168 days) of age.

Cattle—Withdraw 7 days before slaughter. For dairy calves, dairy heifers, and beef cattle only.

A withdrawal period has not been established for this product in pre-ruminating calves.

Do Not Use in Calves to be Processed for Veal

Distributed by:
 SmithKline Beecham Animal Health
 West Chester, PA 19380, USA

942 70-8446